

Title (en)

A METHOD FOR OPTIMIZING AND VALIDATING AN ASSAY FOR DETERMINING THE PRESENCE OR ABSENCE OF A MEDICAL CONDITION

Title (de)

VERFAHREN ZUR OPTIMIERUNG UND VALIDIERUNG EINES TESTS FÜR DEN NACHWEIS DER PRÄSENZ ODER ABSENZ EINES MEDIZINISCHEN ZUSTANDES

Title (fr)

PROCÉDÉ D'OPTIMISATION ET DE VALIDATION D'UN ESSAI PERMETTANT DE DÉTERMINER LA PRÉSENCE OU L'ABSENCE D'UNE CONDITION MÉDICALE

Publication

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Application

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Abstract (en)

[origin: WO2009115920A1] The invention relates to a method for validation of an assay for determining the presence or absence of a medical condition, wherein the nucleic acid has been treated such that all unmethylated cytosine bases are converted to uracils. According to the invention, the method comprises: a) measuring the concentration of the nucleic acid in biological samples; b) allotting the samples based on the measured concentration of the nucleic acid in the sample to a first sample group if the concentration of the nucleic acid is below a given threshold value, or to a second sample group if the concentration of the nucleic acid is above the given threshold value; c) performing an assay for determining the methylation status of the nucleic acid in the sample obtaining methylation signals, and d) applying a first algorithm to the value if the sample was allotted to the first sample group, or a second algorithm if the sample was allotted to the second sample group.

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